Remarks/Arguments

1. In the Office Action mailed March 27, 2003, claims 1-20 are pending and claims 8-20 are withdrawn from consideration. Claim 6 stands rejected, under 35 U.S.C. § 101, for being drawn to non-statutory subject matter, claims 1-7 stand rejected, under 35 U.S.C. § 112, first paragraph, for inadequate written description and for lack of enablement, and claims 1, and 4-7 stand rejected, under 35 U.S.C. § 112, second paragraph, for indefiniteness.

2. In keeping with the restriction election, claim 4 is currently amended to pertain to cells derived from the genetically-modified mouse of claim 1. Support for this amendment is also found in the specification, for example, at page 28, lines 29-31. Claim 1 is amended to recite a mouse rather than a non-human mammal, to add that the mouse is homozygous for the genetic modification to the PDE11A gene, to recite that the mouse demonstrates non-detectable PDE11 activity, and to add phenotypic characteristics. Support for these amendments is found in the specification, for example, in original claim 3, at page 3, lines 11-13, at page 12, lines 22-23, and at page 42, line 4, to page 44, line 6. Accordingly, no new matter is added by amendment.

3. Non-statutory subject matter. Claim 6 is currently cancelled and this rejection is now moot.

4. Written Description. Claims 1-7 stand rejected for inadequate written description on the basis that the specification only describes a mouse genetically modified by targeted gene insertion. To the extent that this rejection focuses upon the claimed species, Applicants note that the claimed subject matter has been restricted to genetically-modified mice and murine cells derived from the genetically-modified mice. To the extent that this rejection focuses upon the method of making the claimed mice, Applicants traverse this rejection and note that the claims at issue are to compositions of matter and not methods. "When the claim is to a composition rather than a process, the written description requirement does not demand that the specification describe technological developments in a way in which the claimed composition is made that may arise after the patent application is filed. See United States Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247, 1251; 9 USP2d 1461 (Fed. Cir. 1989).[...] The written description inquiry, therefore, focuses on a comparison between the specification and the invention referenced by the terms of the claim – not a comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the product is made." Amgen, Inc. v. Hoechst Marion Roussel, Inc. and

Transkaryotic Therapies, Inc., 126 F. Supp. 2d, 69, 150; 57 USPQ2d 1449 (D.C. Mass., 2001). Therefore, alternative methods of making the claimed subject matter, beyond those actually disclosed to make the mice, are not relevant to the written description requirement. For all of the above reasons, Applicants request that the rejections for inadequate written description be withdrawn.

5. Enablement. Claims 1-7 stand rejected for lack of enablement on the grounds that the specification only enables genetically-modified mice generated by targeted gene insertion, not any alternative method, that the specification enables only mice, not non-human mammals, and that the specification only enables the genetically-modified mice that have the phenotype of reduced spermatogenesis or increased capacitation. With respect to the methods of making the mice, Applicants traverse this rejection for reasons that parallel the traversal of the rejection with respect to written description requirements. First, "where the method is immaterial to the claim, the enablement inquiry simply does not require the specification to describe technological developments concerning the method by which a patented composition is made that may arise after the patent application is filed." Amgen, 126 F.Supp.2d at 160, 57 USPQ2d at 1515 (citing Phillips Petroleum, 865 F.2d at 1251, 9 USPQ2d at 1465). Second, "the law makes clear that the specification need teach only one mode of making and using the claimed composition." Amgen, 126 F. Supp.2d at 160; 57 USPQ2d at 1515 (citing Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342, 1361 , 47 USPQ2d 1705, 1719 (Fed. Cir. 1998). Accordingly, any purported unpredictability in the art regarding alternative methods of making the claimed genetically-modified mice and murine cells is not relevant to the enablement requirements as the specification provides a mode of making and using the claimed compositions. With respect to other species besides mice and phenotypic limitations on the mice, Applicants note that amendments to the claims render moot these grounds for rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

6. Indefiniteness. Claims 1 and 4-7 stand rejected for indefiniteness with respect to the term "functionally disrupt" and whether the cells of claims 4-7 are in vivo. Applicants note that the term "functionally disrupted" is defined in the specification, at page 12, lines 6-23, and also note that claim 1 has been amended to recite that the claimed mice demonstrate nondetectable PDE11A activity. In addition, currently amended claim 4 recites that the claimed cells are derived from the genetically-modified mice of claim 1. Withdrawal of this rejection is respectfully requested.

7. Applicants believe that the amendments hereinabove to the claims place the Application in condition for immediate allowance. Therefore, entry of the amendments hereinabove and reconsideration of the Office Action mailed March 27, 2003, 2003 are respectfully requested. Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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